A Pilot Study to Evaluate the Efficacy of Scarguard in the Prevention of Scars

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Abstract

Numerous treatment modalities have been proposed to prevent hypertrophic scars and keloids from forming following a surgical procedure. Scarguard is a newly developed topical medication, which combines silicone, hydrocortisone, and vitamin E, in a clear liquid formulation that forms a protective film. In this open-label pilot study, 12 patients with a history of keloid and hypertrophic scar formation applied Scarguard to a wound following shave excision of a mole. All patients had a second mole removed at the same time, which was not treated with the study medication and served as a control. After 2 months of therapy, most patients reported a reduction of redness and overall appearance of the treated scar, while about half noted that the scar was softer and less raised with treatment. The Investigator noted similar changes. This open label pilot study supports the observation that Scarguard improves scars warranting further investigation to confirm these results.

BACKGROUND

Keloid and hypertrophic scarring develop as a result of a proliferation of dermal tissue following skin injury. In susceptible individuals, scars that become raised, red, and firm may result in itching and pain, and create cosmetic and functional problems. Numerous treatment modalities are available to prevent hypertrophic scars and keloids and minimize disfiguring scars from forming following a surgical procedure. No treatment regimen has been demonstrated to be universally effective[1].

Several modalities have been shown in past studies to have varying degrees of effectiveness in improving the healing of scars. These include pressure, occlusion, silicone, several corticosteroids, and vitamin E. Scarguard (Red Rock Laboratories, Great Neck, N.Y.) is a new, over-the-counter topical medication developed to improve the appearance of scars. The clear liquid formulation, which combines silicone, hydrocortisone, and vitamin E, dries rapidly and forms a clear protective film when applied to skin. The flexible collodion carrier adds occlusion and slight increased surface tension to deliver these multiple modalities.

This investigator noted that many dermatologists and plastic surgeons have incorporated Scarguard into their post surgical regimen. It has been anecdotally reported that the product has a beneficial effect in the stimulation of endogenous collagenase production. Logically, it would seem that combining these accepted technologies would lead to improved scarring. The purpose of this pilot study was to evaluate Scarguard in the improvement of scars following a minor dermatologic surgical procedure.

MATERIALS AND METHODS

Patients who, independent of this study, were noted to have 2 suspicious nevi on their trunk that required removal by shave excision without suture formation were chosen to participate. All twelve adult patients studied had a history of keloid or hypertrophic scar formation with prior removal of a nevus.

After the 2 nevi were removed under local anesthesia, patients were instructed to apply a topical antibiotic ointment to their surgical wounds for a minimum of 14 days and up to 3 weeks to allow the wounds to completely heal. Patients then were instructed to brush on Scarguard twice daily on only one of the 2 healed wound sites. Patients brushed the liquid to one wound site and allowed it to air-dry for 1 minute. The site was left uncovered. Patients continued the treatments daily for 2 months at which time they were evaluated. Both the patient and the examiner, neither of whom were blinded, evaluated the color, contour, texture and overall appearance of the scar.

RESULTS

Measures of improvement were provided by both the

subjects and investigator who either agreed or disagreed that the treated scar, compared to the untreated scar, was less red, less raised, softer, and less noticeable (Table 1). Both the investigator and majority of patients noted improvement in the treated vs. untreated wound in all parameters measured.

Figure 1

Table 1: The Response to Scarguard on Scars

	Patient Evaluation	Investigator Evaluation
Treated Scar		
Less red		
1 month	6	
2 months	9	9
Less Raised		
1 month	2	
2 months	5	6
Softer		
1 month	4	
2 months	6	6
Less noticeable		
1 month	5	
2 months	9	9

Nine of 12 patients reported superior outcomes with Scarguard in the reduction of redness and overall appearance of the treated scar. Six of the patients reported that the scar was softer compared to the untreated scar, and 5 patients noted that the scar was less raised. Generally, overall improvement was noted after 1 month and continued until the end of the 2-month treatment period. No patient reported a worsening in any of the parameters with treatment, and nor were there were any reported adverse reactions such as hyperpigmentation, hypopigmentation, stinging, burning or irritation. All patients were reported to be compliant and found no difficulty in applying the medication to the wound.

The investigator determined that 9 of the 12 patients had a reduction of redness and improved overall appearance of the treated scar, while in 6 patients, the treated scar was superior with regard to texture.

DISCUSSION

This open label pilot study supports the observation that Scarguard, when applied to a wound in patients with a history of hypertrophic scar and keloids formation, improves scars. The multimodality approach of the tested material may in part explain the benefits observed both patients and investigator in this study.

Scarguard contains a 12% silicone gel preparation. Both, silicone gel and silicone sheeting have been previously demonstrated to reduce scar size and erythema[2, 3]. Specifically, the application of silicone after surgical resection has been shown to help prevent the development of hypertrophic scars and keloids in 75% to 85% of cases[4, 5]. Although its exact mechanism is unknown, silicone's prevention of wound desiccation and inhibition of fibroblast production of collagen and glycosaminoglycans, appear to be contributing factors[6].

Corticosteroids have been demonstrated to reduce scars and keloid formation predominantly by reducing collagen synthesis and production of inflammatory mediators and fibroblast proliferation during wound healing[7, 8]. Although intralesional injections are the mainstay of treatment for keloids and hypertrophic scars, mild topical corticosteroids can prevent or decrease abnormal scarring in superficial lesions[9, 10]. The hydrocortisone in the tested formulation, delivered under occlusion by the liquid carrier, may play a role its mechanism of action.

Topical formulations of Vitamin E, as found in the tested product, have been promoted as an aid to wound healing presumably because they have been shown to inhibit collagen synthesis, decrease fibroblast proliferation and reduce inflammation[11]. Furthermore, vitamin E may improve scar characteristics by its hydrating effects. Although one study using vitamin E from oral capsules showed no improvement in the cosmetic appearance of scars[12], in another study, the synergistic effects of vitamin E and silicone were shown to be superior to silicone alone in the treatment of keloids[13].

The occlusive dressing component of the tested material, consisting of a flexible collodion solution, forms a noncontracting dressing when applied to skin and results in both hydration and occlusion of scars. Pressure and compression have been repeatedly demonstrated to prevent and modify keloids and hypertrophic scars formation[14]. The degree of pressure needed to stimulate collagenase production is controversial. Specialized compression dressings and devices have been devised, all with variable degrees of success however, patient compliance often limits their use. The use of an odorless, clear liquid protective and occlusive dressing, providing occlusion and only a slight increase in surface tension may be beneficial and overcome these limitations.

CONCLUSIONS

Both patients and investigator noted improved esthetic effects with Scarguard on the appearance of scars following a minor surgical procedure. This newly developed formulation offers patients an efficacious alternative to aggressive therapeutic options such as intralesional corticosteroid injections and surgical excision. Although the study observations were determined in a small group of patients in a nonblinded fashion, further investigation is warranted to confirm these results.

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